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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/319,156	11/02/1999	GLAUCIA PARANHOS-BACCALA	103514	2490

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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/319,156	PARANHOS-BACCALA ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-9,14,15,28-30,36-38,40-42,45-47,49-51 and 60-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-9,14,15,28-30,36-38,40-42,45-47,49-51 and 60-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 November 1999* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152),
6) ☐ Other: _____.

Detailed Office Action

37 C.F.R. § 1.114

A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection on 24 June, 2004. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicants' submission filed on 24 March, 2004, has been entered.

Status of the Claims

Claims 1, 7-9, 14, 15, 28-30, 36-38, 40-42, 45-47, 49-51, and 60-64 are pending and currently under examination. Applicants are reminded of the restriction requirement set forth in the paper mailed 16 February, 2001. Applicants elected nucleotide sequences encoding the *env* gene in the response filed 16 July, 2001. Presumably, these sequences included SEQ ID NOS.: 6, 9, and 12. Perusal of the disclosure and sequence listing appears to suggest that SEQ ID NO.: 12 is actually directed toward a *gag-pol* coding region and **not** the Env. If this assumption is correct, the claims will only be examined to the extent they read on sequences directed toward the *env* (e.g., SEQ ID NOS.: 6 and 9). Applicants are invited to provide evidence demonstrating that SEQ ID NO.: 12 corresponds to the *env* coding region.

37 C.F.R. § 1.84

The drawings (Figures 13-16) are objected to because they are illegible (i.e., in Fig. 13 the glycosylation box covers up the nucleotide sequence; all of the figures are of poor quality).

Corrected drawing sheets in compliance with 37 C.F.R. § 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet "or "New Sheet "pursuant to 37 C.F.R. § 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will **not** be held in abeyance.

Claim Objections

Claim(s) 1, 14, 15, 26, 28-30, 45-47, 49-51, and 60-64 are objected to because of the following informalities: applicants are reminded of the restriction requirement and election summarized *supra*. Nucleotide sequences corresponding to the env gene were elected for examination on the merits. Nucleotide sequence no. 12 does not appear to correspond to the elected subject matter and should be deleted from the claim. Appropriate correction is required.

35 U.S.C. § 132

The amendment filed 24 March, 2004, is objected to under 35

U.S.C. § 132 because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The following material has been introduced which does not receive support in the original disclosure: the sequence listing included new SEQ ID NO.: 46, which was not previously set forth in any prior sequence listing. Moreover, direct support for this sequence identifier could not be found in the instant application. Applicant is required to **cancel** the new matter in the response to this Office action.

35 U.S.C. § 112, Second Paragraph

Claim 8 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have amended the claim language to include SEQ ID NO.: 46. However, the genomic coordinates and coding potential of this sequence remain to be elucidated. Accordingly, the metes and bounds of the patent protection desired cannot be ascertained.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claim 8 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). Applicants have amended the claim language to include a new sequence identifier (e.g., SEQ ID NO.: 46) which has not previously been identified or set forth. Applicants have failed to provide the genomic coordinates or coding potential of this nucleotide sequence.

Written Description

Claims 1, 7-9, 14, 15, 28-30, 36-38, 40-42, 45-47, and 60-64 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *University of Rochester v. G.D. Searle & Co.*, 69 U.S.P.Q.2d 1886 (C.A.F.C. 2004). The claims have been amended to encompass various nucleotide sequences that share 70%, 80%, 90%, and 95% genetic relatedness to the parent sequences. As previously set forth, to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of nucleic acids.

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using

such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a "**laundry list**" disclosure of every possible moiety does **not** constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties,

functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure form the mere recitation of function and minimal structure is highly unlikely. In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

Moreover, where claims directed toward nucleic acids are concerned, legal precedence also clearly dictates that conception of a chemical compound (e.g., a DNA molecule) is not achieved until reduction to practice has occurred (*University of California* v. *Eli Lilly*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997); *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 U.S.P.Q.2d 1016-1031 (C.A.F.C. 1991); *Fiers v. Sugano*, 25 U.S.P.Q.2d 1601-1607 (C.A.F.C. 1993); *In re Bell*, 26 U.S.P.Q.2d 1529-1532 (C.A.F.C. 1993); *In re Deuel*, 34 U.S.P.Q.2d 1210-1216 (C.A.F.C. 1995)). In *Amgen Inc. v.*

Chugai Pharmaceutical Co. Ltd. the court concluded that "It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated." The significance of conception and reduction to practice was further addressed by the court in *Fiers v. Sugano* where it was emphasized that "Conception is a question of law, reviewed *de novo* on appeal, and if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated; thus, regardless of complexity or simplicity of method of isolation employed, conception of DNA sequence, like conception of any chemical substance, requires definition of that substance other than by its functional utility." Thus, the courts have emphasized that the inventor must clearly and unambiguously identify the salient characteristics and properties of any given claimed nucleotide sequence. It is not sufficient to provide a vague reference to the biological activity of any given nucleotide sequence or some generic method of obtaining it.

The disclosure describes the isolation and characterization of a novel human retrovirus that may be associated with multiple sclerosis. A molecular clone was obtained and the purported nucleotide sequence of the *env* gene ascertained. Thus, **the skilled artisan would reasonably conclude that applicants were in possession of those particular clones containing SEQ ID NOs.: 6 and**

9. Appropriately drafted claim language directed toward these embodiments would be acceptable. However, the broadly recited claim language directed toward fragments, equivalents, and homologous sequences is unacceptable. While this application does provide some nucleotide sequence data, nonetheless, the two sequences identified both correspond to the same *env* gene. The disclosure only provides nucleotide sequence data from a single MSRV isolate. Moreover, the disclosure fails to identify any critical molecular determinants modulating the functional activities of the Env glycoprotein. It has been well-documented in the prior art that single or multiple amino acid substitutions, addtions, or deletions can have profound influences on protein activity. Therefore, the skilled artisan has been asked to guess as to which of the various nucleic acids might retain the desired activity. Additionally, perusal of the specification fails to lead the skilled artisan to any particular sequences.

Furthermore, the court concluded in *In re Gosteli* that the disclosure of a single species is insufficient support for claims directed toward a broader genus. *In re Gosteli*, 872 F.2d 1008, 1010, 10 U.S.P.Q.2d 1614, 1616 (Fed. Cir. 1989). The importance of providing detailed structural information for a representative number of species was also emphasized by the court in *Univ. of Rochester* who stated that the "disclosure contained in the application "just represents a wish, or arguably a plan, for obtaining the DNA," and that "it does not indicate that [the applicant] was in possession of the DNA." *Id.* at 1171. The court added that **a description of DNA requires "a precise definition, such as by structure, formula, chemical name, or physical properties...."** As referenced above, the court said that "[c]laiming all DNA's that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has

arrived." *University of Rochester* v. *G.D. Searle & Co.*, 68 U.S.P.Q.2d 1424 (D.C. W.N.Y. 2003)

Response to Arguments

Applicants traverse and submit that the initial burden is on the PTO to establish that the claimed subject matter is not described by the specification. This argument is not deemed to be persuasive for the reasons clearly set forth above. Applicants have identified a single MSRV and a limited number of env nucleic acids corresponding to the same sequence. The disclosure does not provide the nucleotide sequence of any other closely or distantly related variants.

Applicants further argue that a sufficient number of species have been provided to provide a sufficient written description for the claimed genus of nucleotide sequences. It was emphasized that molecular clones carrying MSRV-I *env* coding sequences were obtained from different sources (e.g., CL6-5/6-3 [SEQ ID NOS: 6 and 7]; C15, which encodes a portion of the MSRV-I envelope; and C15 [SEQ ID NO.: 10]. The identification of a small number of closely related molecular clones is insufficient to support claim language directed toward genetically more diverse sequences (i.e., 70% genetic relatedness). Moreover, the disclosure fails to provide any detailed functional information concerning the envelope region. The courts have repeatedly emphasized that it is the combination of structure and function that is required. *University of California* v. *Eli Lilly*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 U.S.P.Q.2d 1016-1031 (C.A.F.C. 1991). *Fiers v. Sugano*, 25 U.S.P.Q.2d 1601-1607 (C.A.F.C. 1993). Contrary to applicants' assertion, nothing in the disclosure would lead to the skilled artisan to other sequences having the recited degree of variability. Accordingly, the rejection is proper.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, James C. Housel, can be reached at (571) 272-0902. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

01 April, 2005